

Robert Greene Sterne Jorge A. Goldstein David K.S. Cornwell Robert W. Esmond Michael O. Lee Steven R. Ludw John M. Covert Lawrence B. Bugaisky Donald J. Featherstone

Judith U. Kim Timothy J. Shea, Jr. Patrick E. Garrett Heidi L. Kraus Edward W. Yee Albert L. Ferro' Donald R. Banowit Teresa U. Medler Jeffrey S. Weaver Kendrick P. Patterson Vincent L. Capuano Vincent L. Capuano Eldora Ellison Floyd Thomas C. Flala Brian J. Del Buono Virgil Lee Beaston Kimberly N. Reddick

Theodore A. Wood Theodore A. wood Elizabeth J. Haanes Joseph S. Ostroff Frank R. Cottingham Christine M. Lhulier Rae Lynn Prengaman Jane Shershenov Lawrence J. Carroll* George S. Bardmesser Daniel A. Klein* Andrea J. Kamage Tracy L. Muller* LuAnne M. Yuricek* John J. Figueroa Ann E. Summerfield Tiera S. Coston*

Aric W. Ledford* Registered Patent Agents •

Karen R. Markowicz Nancy J. Leith Helene C. Carlson Gaby L. Longsworth Matthew J. Dowd Aaron L. Schwartz Mary B. Tung Katrina Y. Pei Quach Bryan L. Skelton Robert A. Schwartzmar Timothy A. Doyle Jennifer R. Mahalingappa Teresa A. Colella Jeffrey S. Lundgren Victoria S. Rutherford Eric D. Hayes

Of Counsel Kenneth C. Bass III Evan R. Smith

- *Admitted only in Maryland *Admitted only in Virginia •Practice Limited to

December 15, 2003

WRITER'S DIRECT NUMBER: (202) 772-8525 INTERNET ADDRESS: BRIAND@SKGF.COM

Art Unit 1634

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Non-Provisional Patent Application

Application No. 09/517,466; Filed: March 2, 2000

Compositions and Methods for Use in Recombinational Cloning of

Nucleic Acids

Inventors:

Hartley et al.

Our Ref:

0942.4680003/RWE/BJD/JKM

Sir:

Transmitted herewith for appropriate action are the following documents:

- Fifth Supplemental Information Disclosure Statement;
- 2. List of cited references on Form PTO-1449 (9 pages);
- A copy of each of the cited references on Form PTO-1449 (27 documents: 3. AM9, and AR105-AS113); and
- 4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox PLLC.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skgf.com

Commissioner for Patents December 15, 2003 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Attorney for Applicants Registration No. 42,473

RWE/BJD/JKM/acr Enclosures

SKGF 209721v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hartley et al.

Appl. No. 09/517,466

Filed: March 2, 2000

For:

Compositions and Methods for

Use in Recombinational Cloning

of Nucleic Acids

Confirmation No. 4289

Art Unit:

1634

Examiner:

Johannsen, D.

Atty. Docket: 0942.4680003/RWE/BJD/JKM

Fifth Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Fifth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Third Supplemental Information Disclosure Statement filed on June 17, 2003, and Applicants' Fourth Supplemental Information Disclosure Statement, filed electronically herewith, in connection with the above-captioned application. A copy of each document is also provided.

The Examiner is referred to the following list of related, co-pending patent applications:

U.S. Patent Application No. 09/984,239, filed October 29, 2001, inventors Brasch et al., submitted herewith as Document AS112;

U.S. Patent Application No. 10/396,696, filed March 26, 2003, inventors Hartley et al., submitted herewith as Document AT112;

- U.S. Patent Application No. 10/454,793, filed June 5, 2003, inventors Chesnut *et al.*, submitted herewith as Document **AR113**;
- U.S. Patent Application No. 10/640,422, filed August 14, 2003, inventors Cheo *et al.*, submitted herewith as Document **AS113**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Fifth Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Attorney for Applicants Registration No. 42,473

Date: <u>Dec. 15, 2003</u>

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

::ODMA\MHODMA\SKGF_DC1;197391;1 SKGF Rev 1/24/02 mac; 8/04/03 svb



ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM 09/5

APPLICATION NO. 09/517,466

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Hartley et al.
FILING DATE
March 2, 2000

GROUP 1634

					March 2, 2000	[]	L634	
				U.S. PAT	ENT DOCUMENTS			
EXAMINER		1						
NITIAL	 	DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DAT
	AA	 						
	AB AC	ļ				 		
	AD	1				1		
	AE	1				<u> </u>		
	AF	1				 		
	AG	1						
	AH	1						
	AI							
	AJ							
	AK				1			
				FOREIGN P	ATENT DOCUMENTS			
EXAMINER INITIAL		DOCUI	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATIC
			•					Ye
	AL	 		<u> </u>		 		1
	AM9	WO 96	6/40722 A1	12/19/1996	WIPO			Ye
	AN							Ye
	AO							Ye
								Ye
	AP		UPP /Traludin	a Author Ti	ltle, Date, Pertinent Pag]1
	AR	105	Saccharomyce.	s cerevisiae:	"Regulated expression Nuclear entry and biol 354-1358, National Acad	ogical	consequence	s," Proc.
	AS	Bauer, C.E., et al., "Extent of Sequence Homology Required for Bacteriophage Lambda Site-specific Recombination," J. Mol. Biol. 181:187-197, Academic Press, Inc. (1985).						
	AT	105	transcription	nal terminato	1., "A bacterial repress or can block upstream ac illan Journals, Ltd. (19	tivatio		
EXAMINER						DATE	CONSIDERED	
	hrough ication	citati to Ap	ion if not in		er or not citation is i and not considered. In			

FORM PTO-1449
FIFTH SUPPLEMENTAL

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM

APPLICATION NO. 09/517,466

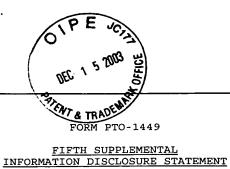
APPLICANT

Hartley et al.

FILING DATE

GROUP 1634

					March 2, 2000	1	.634				
U.S. PATENT DOCUMENTS											
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE			
	AA	-									
	AB										
	AC										
	AD										
	AE										
	AF										
	AG										
	АН										
	AI										
	AJ										
	AK										
	FOREIGN PATENT DOCUMENTS										
EXAMINER							arm ar 1 a a				
INITIAL	 	DOCU.	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION			
	AL							Yes No			
			•••					Yes			
	AM	<u> </u>						No			
	AN							Yes No			
	AO							Yes No			
								Yes			
	AP	<u> </u>				<u> </u>	<u> </u>	No			
		OT	HER (Includin	g Author, Ti	tle, Date, Pertinent Pag	es, etc	:.)				
	AR	<u>106</u>	TcR and KmR c	assettes wit	ckernagel, W., "Gene dis h the option of Flp-cata cerminant," <i>Gene 158</i> :9-1	lyzed e	xcision of	the			
	AS	Collis, C.M., and Hall, R.M., "Expression of Antibiotic Resistance Genes in the Integrated Cassettes of Integrons," Antimicrobial Agents Chemother. 39:155-162, American Society for Microbiology (1995).									
	AT	106 /	Current Prote	ocols in Mole	utagenesis Using the Pol ecular Biology 1:8.5.1-8 Inc. (1997).						
EXAMINER						DATE	CONSIDERED				



ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM

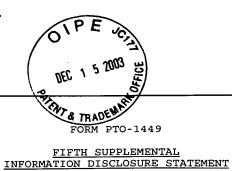
APPLICATION NO. 09/517,466

APPLICANT

Hartley et al.

FILING DATE March 2, 2000 GROUP 1634

U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
-	AA							
	AB							
	AC							
	AD							
	AE							
	AF							
	AG							
	AH	L				<u> </u>		
	AI							
	AJ		· · · · ·					
	AK						<u> </u>	<u> </u>
				FOREIGN PA	ATENT DOCUMENTS	1	r	
EXAMINER INITIAL		DOCT	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
INITIAL	 	DOCO	MENI NUMBER	DATE	COUNTRY	CLASS	30B-CLASS	Yes
	AL							No
	AM							Yes No
				Ì		<u> </u>		Yes
	AN							No
	AO					ļ <u> </u>		Yes No
1	AP							Yes No
		OT	HER (Including	g Author, Ti	tle, Date, Pertinent Pag	es, etc	.)	· · · · · · · · · · · · · · · · · · ·
	AR	107	Enquist, L.W.	., and Weisbe	erg, R.A., "The Red Plaq on Defective Variants of demic Press, Inc. (1976)	ue Test Bacter	: A Rapid Me	
	AS	<u>107</u>	in Current P	rotocols in N	erived from Plasmids: In Molecular Biology 1:1.5. Sons, Inc. (1998).			
	AT	107 /	Mediate Inve	rsion of a Sp "Salmonella,	K., "Trans-acting Genes becific DNA Segment Invo ' Cold Spring Harb. Symp (1981).	lved in	Flagellar E	Phase
EXAMINER						DATE	CONSIDERED	



ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM

APPLICATION NO. 09/517,466

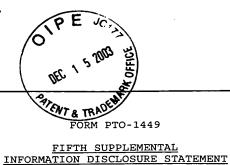
APPLICANT

Hartley et al.

FILING DATE March 2, 2000 GROUP 1634

					March 2, 2000		1634		
				U.S. PAT	TENT DOCUMENTS				
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA								
	AB								
	AC								
	AD				1				
	AE								
	ÁF								
	AG						L.		
	АН								
	AI						_		
	AJ								
	AK								
				FOREIGN P	ATENT DOCUMENTS				
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
	AL							Yes No	
	АМ							Yes No	
	AN							Yes No	
	AO							Yes No	
	AP							Yes No	
		OT	HER (Includin	g Author, Ti	tle, Date, Pertinent Pag	jes, etc	2.)		
	AR	108 /							
	AS	108	Klippel, A., et al., "Isolation and characterization of unusual gin mutants," EMBO J. 7:3983-3989, IRL Press, Ltd. (1988).						
	Koch, C., et al., "Escherichia coli host factor for site-specific DNA inversion: Cloning and characterization of the fis gene," Proc. Natl. Acad. Sci. USA 85:4237-4241, National Academy of Sciences (1988).								
EXAMINER	1		•			DATE	CONSIDERED		





ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM

APPLICATION NO. 09/517,466

APPLICANT

Hartley et al.

FILING DATE March 2, 2000

GROUP 1634

				U.S. PAT	ENT DOCUMENTS			
EXAMINER	ľ	1		0.0. 1				
INITIAL		DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA					:		
	AB							
	AC							
	AD							
	AE							
	AF							
	AG							
	AH							
	AI							
	AJ						ļ. <u>.</u>	
	AK							
				FOREIGN PA	ATENT DOCUMENTS			
EXAMINER INITIAL		DOCT	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
INITIAL	-	DOCO	MENI NUMBER	DATE	COONTRI	CLASS	30B-CHA33	Yes
	AL							No.
	АМ							Yes No
, , , , , , , , , , , , , , , , , , , ,	AN							Yes No
	AW	ļ						Yes
	AO	<u> </u>						No Yes
	AP							No
		OT	HER (Includin	g Author, Ti	tle, Date, Pertinent Pag	es, etc	.)	
,	AR	109 /			"Expression of an <i>Esche</i> risiae," Mol. Gen. Genet			
	AS	109 /	Miller, H.I., et al., "int-h: an int Mutation of Phage λ That Enhances Site-Specific Recombination," Cell 20:721-729, MIT (1980).					
Y	AT	109 /	csrA and a Pi	reviously Unr	dence for Involvement of the decognized Gene tldD, in F," J. Mol. Biol. 256:	the Co	ntrol of DNA	A Gyrase by
EXAMINER						DATE	CONSIDERED	



FORM PTO-1449

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

next communication to Applicant.

ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM APPLICATION NO. 09/517,466

APPLICANT

Hartley et al.

FILING DATE March 2, 2000 GROUP 1634

U.S. PATENT DOCUMENTS										
EXAMINER INITIAL		חסמוו	MENT NUMBER	DATE	NAME	CLASS SUB-CLASS FILING DATE				
INTITAL	AA	DOCO.	TOTAL TOTAL	27712		CLIAGO	DOD CHADO	TIBING BITE		
. ,	AB									
	AC									
	AD									
	AE									
	AF									
	AG									
	AH									
	AI									
	AJ		·							
	AK			<u> </u>		<u> </u>		<u> </u>		
				FOREIGN PA	ATENT DOCUMENTS	T				
EXAMINER INITIAL		DOCUI	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION		
	AL							Yes No		
	AM							Yes No		
	AN							Yes No		
								Yes		
	ÃO							No Yes		
	AP							No.		
		OT	HER (Includin	g Author, Ti	tle, Date, Pertinent Pag	es, etc	.)			
	AR	110		y into Mammal	, "Bacteriophage Lambda ian Cells," <i>Mol. Cell.</i> (1985).					
	AS	<u>110</u>	Osuna, R., et al., "Identification of two functional regions in Fis: the N-terminus is required to promote Hin-mediated DNA inversion by not λ excision," EMBO J. 10:1593-1603, Oxford University Press (1991).							
	AT	Sambrook, J., et al., Molecular Cloning: A Laboratory Manual, 2nd ed., Cold Spring Harbor Laboratory Press, New York, pp. 16.6-16.8 (1989).								
EXAMINER			<u> </u>			DATE	CONSIDERED			
EXAMINER: In Draw line th	nitial rough (if re	eference consi ion if not in	dered, wheth conformance	er or not citation is in and not considered. In	n confor	rmance with opy of this	MPEP 609. form with		



FORM PTO-1449

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM

APPLICATION NO. 09/517,466

APPLICANT

Hartley et al.

FILING DATE March 2, 2000 GROUP 1634

U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA							·
	AB							
	AC							
	AD		-					
	AE							
	AF							
<u>., , , </u>	AG			<u> </u>				
	AH							
	AI							
	AJ			 				
	AK							
		1		FOREIGN PA	ATENT DOCUMENTS	r	1	<u> </u>
EXAMINER INITIAL		DOCIT	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
INITIAL		DOCO	MENT NOMBER	DATE	COONTRI	CHASS	BOB-CHASS	Yes
	AL							No
	AM							Yes No
								Yes
	AN		•••	}				No Yes
	AO							No
-	AP							Yes No
		OT	HER (Includin	g Author, Ti	tle, Date, Pertinent Pag	es, etc	.)	
	AR	<u>111</u> ./	cells by the	Cre recombin	N., "Site-specific DNA mase of bacteriophage P1 cademy of Sciences (1988	," Proc		
	AS	111	Sauer, B., "Expression and Functioning in Yeast of a Bacterial Site Specific Recombination System," <i>J. Cell. Bio. Chem. Supp.</i> 10(b):242, Abstract No. I340, Alan R. Liss, Inc. (1986).					
	AT	111	Stryer, L., p. 610 (1981)		2nd ed., W.H. Freeman	and Co.	, San Franc	isco, CA,
EXAMINER						DATE	CONSIDERED	

Page 8 of 9



FORM PTO-1449

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM	APPLICATION NO. 09/517,466
APPLICANT Hartley et al.	
FILING DATE March 2. 2000	GROUP 1634

. <u>INFO</u>	KMATIO	<u> </u>	LOSORE STATES	ESIV I	March 2, 2000		634				
				U.S. PAT	ENT DOCUMENTS						
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE			
	AA										
	AB		•								
	AC										
	AD										
	AE										
	AF	<u></u>									
	AG	<u></u>				<u> </u>					
	AH										
	AI										
	AJ	<u> </u>									
	AK										
				FOREIGN PA	ATENT DOCUMENTS	_					
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION			
	AL							Yes No			
	AM							Yes No			
	AN					E		Yes No			
•	AO							Yes No			
	AP							Yes No			
		OT	HER (Includin	g Author, Tit	tle, Date, Pertinent Pag	jes, etc	:.)	<u> </u>			
	AR	<u>112</u>	Vetter, D.,	et al., "Site	e-specific recombination SA 80:7284-7288, Nationa	of yea	st 2-μm DNA				
	AS	112 /		Copy of co-pending U.S. Application No. 09/984,239, inventors Brasch et al., filed on October 29, 2001 (NOT PUBLISHED).							
	AT 112 Copy of co-pending U.S. Application No. 10/396,696, inventors Hartley et al., filed on March 26, 2003 (NOT PUBLISHED).										
EXAMINER						DATE	CONSIDERED				

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

b



FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 0942.4680003/RWE/BJD/JKM APPLICANT

APPLICATION NO. 09/517,466

Hartley et al.

FILING DATE March 2, 2000

GROUP 1634

U.S. PATENT DOCUMENTS									
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA								
	AB								
	AC								
	AD								
	AE								
	AF								
	AG								
	AH	<u> </u>							
	AJ								
<u> </u>	AK	ļ—-							
	me			FOREIGN P	ATENT DOCUMENTS		l		
EXAMINER							<u> </u>		
INITIAL		DOCU	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
	AL							Yes No	
	AM							Yes No	
	AN							Yes No	
								Yes	
	AO							No Yes	
	AP	<u> </u>				<u></u>	<u> </u>	No	
	OTHER (Including Author, Title, Date, Pertinent Pages, etc.) AR 113 Copy of co-pending U.S. Application No. 10/454,793, inventors Chesnut et al., filed on June 5, 2003 (NOT PUBLISHED).								
	AS	<u>113</u>	Copy of co-pending U.S. Application No. 10/640,422, inventors Cheo et al., filed on August 14, 2003 (NOT PUBLISHED).						
EXAMINER	AT					DATE	CONSIDERED		
						'			